DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Lasering S.r.l
% Transamerican Technologies International
Mr. Allen R. Howes
2246 Camino Ramon
San Roman, California 94583

JUL 2 2 2011

Re: K110984
Trade/Device Name: SLIM Evolution II CO2 Laser and Delivery Device Accessories
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: ONG, GEX
Dated: June 1, 2011
Received: June 22, 2011

Dear Mr. Howes:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number K110984

Device Name: SLIM Evolution II CO2 Laser and Delivery Device Accessories.

Indications For Use:

The SLIM Evolution II CO2 Laser and delivery device accessories are intended for use in surgical applications that require ablation, vaporization, excision, incision and coagulation of soft tissue in dermatology and plastic surgery, general surgery, gynecology, podiatry, dental and otorhinolaryngology.

Dermatology, Plastic Surgery and General Surgery procedures.

Laser skin resurfacing
Treatment of furrows and wrinkles
Removal of skin tags, actinic keratosis, acne scars, keloids, tattos, telangiectasia, squamous and basel cell carcinoma, warts and uneven pigmentation.
Treatment of cysts, abscesses, hemorrhoids and other soft tissue applications.
Blepharoplasty
Site preparation for hair transplants
MiXto fractional scanner only for treatment of wrinkles and skin resurfacing

Prescription Use ____X____ AND/OR Over-The-Counter Use _____
(part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Neil R.P. Ogden for mkm
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K110984

Indications for Use

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Device Name: SLIM Evolution II CO2 Laser and Delivery Device Accessories.

Indications For Use: Continued from previous page

Dental procedure including.
Periodontal procedures such as – gingivectomy, removal of hyperplasias,gingivoplasty (incision and excision)
Oral Surgery procedures such as – aphous ulcer excision, frenectomy, benign/malignant lesion ablation, operculectomy and homeostasis

Podiatry procedures.
Ablation, vaporization and excision of soft tissue lesions such as ingrown nail, fungal nail, porokeratoma, matrixectomy and verrucae vulgares.

Otorhinolaryngology (ENT) procedures.
Treatment of leukoplakia of larynx, nasal obstruction, rhinophyma, verrucrea vulgares, choanal atresia, rhinophyma, LAUP and papillomatosis polyps.

Gynecology
Treatment of condyloma acuminata, cervical intraepithelial neoplasia, leukoplakia and vulvar/vaginal intraepithelial neoplasia, cervical dysplasia.
Laparoscopic treatment endometrial lesions, ablation of endometriosis, fimbroplasty,
Tubal microsurgery, salpingostomy, histerectomy, uterine myomas and fibroids

Prescription Use ____X_____ AND/OR Over-The-Counter Use _____
(part21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE ABOVE THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Mark Pogrea for mkm
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices